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674521-2001.1

REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-6, 9-14, 17-21 and 35-50 are under examination in this application. Claims 1-6, 10-12, 14, 17, 18, 20, 21 and 25 have been amended; claims 37-50 have been added to round out the scope of protection to which Applicants are entitled.

Support for the amendments can be found throughout the specification. Specifically, support for new claims 37-50 can be found in the paragraph bridging pages 23 and 24 of the specification. The remaining amendments have been made to correct dependence and address formal issues.

No new matter has been added by these amendments.

It is submitted that claim 9 should have been deemed allowable, as was not included in any rejection. It is further submitted that claim 11 was erroneously included in the rejection under 35 U.S.C. §112, second paragraph, as it depends from claim 9, not claim 10. As such, it is assumed that claim 11 is allowable as well. Analogously, claim 36, which also depends from claim 9, should be allowable.

These claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments of the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE REJECTIONS UNDER 35 U.S.C. § 112, 1<sup>ST</sup> PARAGRAPH, ARE OVERCOME

Claims 1-6, 14, 17-18, 33-36 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking adequate written description. The rejection is traversed.

The Office Action alleges that the broadest embodiments potentially encompass any eukaryotic cell type that might harbor a retrotransposable element. The claims have been amended to depend directly or indirectly from claim 12, which claims pCal specifically, rendering this rejection moot.

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Claims 12, 14 and 19-21 were rejected under 35 U.S.C.112, first paragraph, as allegedly lacking adequate written description. These rejections are traversed.

The Office Action alleges that there is no literal support in the instant application for "a nucleic acid that hybridizes under stringent conditions to the nucleotide sequence of (a)", and that this limitation constitutes new matter. Applicants disagree and direct the Examiner's attention to the section of the specification beginning on page 26, line 7. Applicants urge that these parts of the specification provide literal support to the above-described limitation, and therefore, do not constitute new matter.

The Office Action further alleges the instant specification does not provide a basis for envisioning the embodiments encompassed by a sequence with 65% similarity to the sequence of pCal. As admitted on page 7 of the Office Action, there is clearly written description for the nucleotide sequence of SEQ ID NO: 3. The claimed nucleotide sequence of claim 12 is described functionally and structurally by a sequence identifier, hybridization conditions and percent identity. Hybridization techniques under stringent conditions were conventional in the art at the time of filing, as were techniques for determining sequence identity. A person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the stringent hybridization conditions and the percent identity limitations set forth in the claim yield structurally similar polynucleotides. Therefore, a representative number of species is disclosed, and claims 12 and 19, drawn to a genus of nucleic acids that hybridize with, or have sequence identity to, a given sequence and have a specified, measurable activity, are adequately described.

In that regard, the Examiner's attention is drawn to Example 14 of the USPTO's "Synopsis of Application of Written Description Guidelines". Example 14 presents a fact pattern that is analogous with that of the instant application. The claim in Example 14 recites the structure of the claimed protein, in the form of a SEQ ID NO and variants with a particular percent identity to the recited sequence, and function in the form of identifying the reaction that the protein catalyzes (i.e. its enzymatic activity). Claim 12 of the instant application recites (1) structure of the claimed molecule in the form of a SEQ ID NO, and variants with 65% identity to the recited sequence, and (2) function of the claimed sequence in the form of its retrotransposon character. As discussed in Example 14, even if the claimed SEQ ID NO is the only species disclosed, it is representative of the genus because all members of the genus have the claimed

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level of identity with and function of the protein described by the reference sequence. Therefore, according to Example 14 of the Written Description Guidelines, claims 12 and 19, as presented herein, meet the written description requirement of 35 U.S.C. §112, first paragraph.

The claims are believed to be in compliance with 35 U.S.C. §112; and reconsideration and withdrawal of the rejections thereunder are requested.

**III. THE REJECTIONS UNDER 35 U.S.C. § 112, 2<sup>nd</sup> PARAGRAPH, ARE OVERCOME**

Claims 10-14 and 19-21 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejections are traversed.

Claim 10(b) has been amended for clarity to recite "nucleotide sequence encoding an integration factor", and the Examiner is thanked for his suggestion in that regard.

With respect to the rejection of claims 12 and 19, and dependent claims, Applicants respectfully urge that stringent hybridization conditions are described in the specification, for example, on pages 26-28. Moreover, Applicants urge that the term "stringent hybridization conditions" is well known and understood in the art. The Examiner's attention is particularly drawn to the paragraph beginning on page 28, line 10, of the specification. Sambrook, "Molecular Cloning, A Laboratory Manual" second ed., CSH Press, Cold Spring Harbor, 1989 and "Nucleic Acid Hybridization, A Practical Approach", Hames and Higgins eds., IRL Press, Oxford, 1985 are cited and were incorporated into the application by reference. These guides clearly define stringent hybridization conditions and are widely used for variety of hybridization protocols by the skilled artisan.

In view of these arguments and amendments, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, are requested.

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**CONCLUSION**

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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